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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/273,957	03/22/1999	HUAMING WANG	GC477C1	7787
5100	7590	01/24/2006		
GENENCOR INTERNATIONAL, INC. ATTENTION: LEGAL DEPARTMENT 925 PAGE MILL ROAD PALO ALTO, CA 94304			EXAMINER WALICKA, MALGORZATA A	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/273,957	<b>Applicant(s)</b> WANG ET AL.	
	<b>Examiner</b> Malgorzata A. Walicka	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-14 and 60-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-14, 60-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The finality of the Office Action of May 12, 2002 is withdrawn in a favor of the Office Action bellow. The examiner acknowledges the Response to Advisory Action Mailed December 19, 2002 and Final Office Action Mailed May 21, 2002, which was filed January 13, 2003. The Response comprises amendment to the claims and remarks. The amendment to the claims has been entered. Pending claims 8-14 and 60-65 are the subject of this Office Action.

### **Detailed Office Action**

#### **1. Rejections**

##### ***1.1. 35 USC section 112, first paragraph***

##### ***1.1.2. Rejections for lack of written description***

Claims 8-14 and 60-65 are rejected rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8 and 9 are directed to purified oxidase from genus *Sachybotrys*, wherein said enzyme comprises at least one antigenic determinat with a phenol oxidizing enzyme form *Stachybotrys parvispora* MUCL accession number 38996 or *Stachybotrys chartarum* MUCL accession number 38898, as measured by an immunoprecipitation line by Ouchterlony technique.

The limitations of claims 8 and 9 do not impose sufficient functional and structural characteristics on the large genera of claimed enzymes. Isolated proteins that are positive in Ouchterlony test are not unambiguously identified because the antigenic determinant (an epitope) of a protein can consists of as few as five to 10 amino acids. Five to ten amino acids in common is not an identifying structural characteristic of a genus of enzymes consisting of several hundred of amino acids. Any five–ten amino acids are unlikely to impart the functional features on the protein that is positive in the test. Furthermore, although the specification teaches on page 34 that *M. verrucaria* bilirubin oxidase does not react with antibodies specific to the oxidases purified from *Stachybotrys parvispora* MUCL accession number 38996 or *Stachybotrys chartarum* MUCL accession number 38898, Applicant do not describe proteins that react with antibodies and had other features of the purified enzymes of *S. parvispora* and *chartarum*. Applicant do not teach a protein positive in Ouchterlony test and having activity against the substrates ABTS, syringalizin and DMP at 20°C and 40 °C and pH optima with said substrates similar to that of the oxidases purified from *Stachybotrys parvispora* MUCL accession number 38996 or *Stachybotrys chartarum* MUCL accession number 38898. For that reasons, one having skills in the art is not convinced that Applicants were in possession of the broadly claimed invention at the time the application was filed.

Claim 10 and 11 and dependent claims 60-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a

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way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10 and 11 are directed to oxidases acting on an extremely large genus of colored compounds, wherein the enzymes are obtained from *Stachybotrys parvispora* or *Stachybotrys chartarum* have molecular weight of about 38 and or 30.9 kD.

Applicants argue in the responses to the previous Office Actions that they described the term colored compound sufficiently, and teach that the oxidizing enzymes of the invention are capable of oxidizing a wide variety of dyes and colored compounds having different chemical structure and listed in Colour Index. Applicants' arguments were thoroughly considered, but they have been found unpersuasive. Claims 10-11 still recite an extremely large genus of colored compounds and Applicant did not show that the claimed enzymes act on all these compounds. Applicants teach that the enzyme from *Stachybotrys parvispora* MUCL accession number 38996 acts on 19 chemicals, i.e., three substrates ABTS, syringaldazine and DMP (Table 1A, page 27 of the specification), 15 dyes of different structures, Table 3, page 31-32, as well as on 2-methoxyphenol (guaiacol). The enzyme of invention isolated from *Stachybotrys chartarum* MUCL accession number 38898 was shown to act on ABTS and DMP (Table 1B, page 28). Providing 19 and 2 (included in 19) chemical compounds on which the enzymes act is not identifying the two genera of dyes or color compounds comprising many thousands of chemicals. Providing these 19 or 2 chemicals is also not sufficient for identifying all species of subgenera of porphyrins, carotenoids and anthocyanins or

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Mailrad reaction products as broadly claimed by claims 64 and 65 which recite any species of named subgenera of color substances.

In addition, claims 10 and 11 and dependent claims 64-65 are rejected for reciting the limitation of "increase of apparent molecular weight after boiling". It is not so much that the molecular weight after boiling was increased, but three bands were formed from one band, in case of both enzymes. The bands had molecular weights of 70 kDa, 45 kDa and 22.1 kDa instead of 38 kDa for *S. parvispora*, and 58 kDa, 46 kDa, 19.7 kDa instead of 30.9 kDa for *S. chartarum*; page 2, last paragraph. Thus the language "an increase in apparent molecular weight after boiling" does not describe what was observed. A skilled artisan can as well say that molecular weight are increased as he /she can say they are decreased. Furthermore, one having skills in the art realizes that denaturation of proteins during boiling very often leads to increase of molecular weight, thus this is not necessary an identifying feature of the claimed proteins.

In conclusion, claims 10, 11 and 60-65 are rejected because of lack of sufficient description of the invention. One having skills in the art is not convinced in that Applicants were in possession of the claimed invention at the time the application was filed.

#### *2.2.2. Rejection for scope of enablement*

Claims 8-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the oxidases from

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1) *Stachybotrys chartarum* MUCL accession number 38898 set forth by SEQ ID NO: 2;

2) *Stachybotrys parvispora* MUCL accession number 38996 identified by the features recited in claims 12-14,

does not reasonably provide enablement for a purified oxidase from genus *Sachybotrys*, wherein said enzyme comprises at least one antigenic determinant with a phenol oxidizing enzyme from *Stachybotrys parvispora* MUCL accession number 38996 or *Stachybotrys chartarum* MUCL accession number 38898, as measured by an immunoprecipitation line by Ouchterlony technique.

The claims are not enabled because although the Applicants refer to Ouchterlony technique the article is not incorporated by reference and is improperly quoted; see page 33, second paragraph of the specification. Even if the quotation was proper, Applicants force the skilled artisan to experimentation which is not routine, because one skilled in the art had to isolate the enzymes from *Stachybotrys chartarum* MUCL accession number 38898 and *Stachybotrys parvispora* MUCL accession number 38996; then one skilled in the art had to make antibodies. In the next step one skilled in the art had to make isolates from any genus of *Sachybotrys* and test them using Ouchterlony technique. Even if the one finds a protein positive in the Ouchterlony test there is no warranty that the protein will have the same molecular weight, and other features recited by claims 12-14 for the enzyme from *S. parvispora* or will have molecular weight as recited for *S. chartarum* in claim 11. The probability of obtaining the claimed invention is very low, because claims 8 and 9 do not provide other identifying

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characteristics of the claimed oxidases than a very minor immunological limitation of their structure. Without instructing as to the amino acid structure of the claimed enzymes or identifying features that are recited in claims 12-14 the skilled artisan is forced to undue experimentation.

Claims 10 and 11 and dependent claims 60-61 and 64-65 are rejected because the specification while being enabling for 19 dyes in case of the enzyme from *S. parvispora*, and 2 (included in the group of 19) in case of *S. chartarum*, is not enabling for any dye or colored compound whose number is at least several thousand. See also the above rejection for lack of written description. Providing 19 dyes is not a sufficient guidance for any colored compounds or any dye. One skilled in the art concludes that without identifying the particular dyes of compounds on which the claimed enzymes act, experimentation left to those skilled in the art has a low probability of success and is improperly undue.

## 2. Conclusion

All claims are rejected. As indicated in previous Office Actions, the instant application contains an allowable subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.

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Patent Examiner



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